IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, THE STATE OF CALIFORNIA, THE DISTRICT OF COLUMBIA, THE STATE OF DELAWARE, THE STATE OF FLORIDA, THE STATE OF HAWAII, THE STATE OF ILLINOIS, THE COMMONWEALTH OF MASSACHUSETTS, THE STATE OF NEVADA, THE STATE OF NEW MEXICO, THE STATE OF NEW YORK, THE STATE OF TENNESSEE, THE STATE OF TEXAS, AND THE COMMONWEALTH OF VIRGINIA, *AND* THE STATE OF WISCONSIN *EX REL.* LAUREN KIEFF,	)	CIVIL ACTION
Plaintiffs,	)	
vs.	)	
BRISTOL-MYERS SQUIBB COMPANY	)	
Defendant.	)	

FILED UNDER SEAL

PLAINTIFFS' COMPLAINT
PURSUANT TO THE FEDERAL FALSE CLAIMS ACT,
31 U.S.C. §§ 3729 *ET SEQ.* AND PENDENT STATE FALSE CLAIMS ACTS

The *qui tam* Relator, Lauren Kieff ("Relator"), on behalf of the United States of America, The State of California, The District of Columbia, The State of Delaware, The State of Florida, The State of Hawaii, The State of Illinois, The Commonwealth of Massachusetts, The State of New Mexico, The State of New York, The State of Nevada, The State of Tennessee, The State of Texas, and The Commonwealth of Virginia and the State of Wisconsin (hereinafter referred to as the "Relator States") brings this action against Bristol-Myers Squibb Company ("Bristol") for

violations of the Federal False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, as well as for violations of the following state false claims acts: The California False Claims Act, Cal. Gov't Code §§ 12650 *et seq.*; The District of Columbia False Claims Act, D.C. Code Ann. §§ 2-308.03 *et seq.*; The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, §§ 1201 *et seq.*, The Florida False Claims Act, Fla. Stat. §§ 68.081 *et seq.*; The Hawaii False Claims Act, Haw. Rev. Stat. §§ 661-21 *et seq.*; The Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. Ann. §§ 175/1 *et seq.*; The Massachusetts False Claims Act, Mass. Ann. Laws. Ch. 12, §§ 5A *et seq.*; The New Mexico False Claims Act, N.M. Stat. Ann. §§ 27-14-1 et seq.; The New York False Claims Act, CLS St. Fin. §§ 187 et seq.; H 468, 46th Leg., 2d Reg. Sess. (N.M. 2004);Nevada Submission of False Claims to State or Local Government NRS 357.010 *et seq.;* The Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-171 *et seq.*; The Texas False Claims Act, Tex. Hum. Res. Code §§ 36.001 *et seq.*; The Virginia Fraud Against Taxpayers Act, Va. Code §§ 8.01-216.1 *et seq.* and the Wisconsin False Claims for Medicaid Assistance Act, Wis. Stats. §§ 20.931 (hereinafter referred to as the "State False Claims Acts") to recover all damages, civil penalties and all other recoveries provided for under the Federal False Claims Act and the State False Claims Acts.

I.
SUMMARY OF THE ACTION

1. This case involves Bristol's drug, Pravachol (Pravastatin Sodium), one of the class of drugs known as statins. Statins, which are administered orally and which include drugs such as Lipitor, Zocor and Crestor, lower cholesterol levels primarily by blocking the formation of cholesterol in the liver and by increasing the liver's ability to remove LDL ("bad") cholesterol from the blood. By improving cholesterol levels, statin drugs have proven to be

effective in reducing the risk of heart attack and death. They are some of the most commonly prescribed drugs in the United States. Sales of statin drugs in the United States for the year 2004 topped $15 billion dollars.

2. The relevant National Drug Codes (NDCs) for Pravachol at issue in this case include:

10 mg, 90's	00003-5154-05
20 mg, 90's	00003-5178-05
20 mg, 100's	00003-5178-06
40 mg, 90's	00003-5194-10
80 mg, 90's	00003-5195-10

All references to Pravachol which follow pertain to these five NDC numbers.

3. Since approximately 1995, defendant Bristol has been selling and marketing Pravachol for the treatment of elevated cholesterol and chronic heart disease. Initially, Pravachol competed very successfully within its class. However, after several years, sales growth began to stall. By 1999 Pravachol's share of the statin market was shrinking as competitors like Lipitor enjoyed increased success. New competition entered the statin market as well, such as Crestor and Vytorin. Head-to-head drug studies hurt Pravachol sales also as the drug came to be perceived as less effective than other statins. Meanwhile, it faced the loss of patent protection in early 2006 at which time a generic formulation of Pravachol would likely capture the lion's share of Pravachol sales.

4. In the face of these competitive threats, Bristol made a two-pronged response. First, at least as early as March 2001, it instituted a multi-faceted nationwide campaign, directed at both physicians and the public, to promote sales of Pravachol for uses for which it had never

received FDA approval. For instance, it promoted the drug as the only one approved for lowering the risk of stroke (the third leading cause of death in the United States) whether or not the patient has clinically evident coronary heart disease (CHD). In truth, not only was Pravachol's approval as it pertained to stroke prevention limited to the subset of patients who had clinically evident CHD, another statin, Zocor, in fact *had* received FDA approval for the reduction in the risk of stroke in patients who did not have clinically evident CHD.

5. Second, in the fourth quarter of 2002 Bristol instituted a hospital marketing strategy whereby it offered to private hospitals nationwide the opportunity to buy Pravachol at prices that were discounted by over 90% off of its wholesale price, provided the hospital agreed to place Pravachol in an "unrestricted" position on its drug formulary. As explained herein, the level at which Bristol set the discount was a calculated attempt to treat the price hospitals were paying for the discounted Pravachol as "nominal" for purposes of the Medicaid Rebate Best Price calculation so that Bristol would not have to offer these Pravachol discounts to Medicaid. In or around October 2004 Bristol began offering an even greater discount to hospitals. Under this special offer, which expired at the end of November 2004, (as did the entire nominal pricing program), private hospitals nationwide who had previously agreed to place Pravachol in an unrestricted position on its hospital drug formulary could purchase bulk supplies of Pravachol at the price of just 1/100th of a penny per pill provided, as before, that in exchange for this opportunity they committed to keeping Pravachol in an unrestricted position on its formulary. Hospitals were allowed to purchase as much Pravachol as necessary to meet their needs through the end of 2004 and throughout 2005, a highly unusual offer.

6. Bristol sought to have Pravachol placed in an unrestricted position on hospital formularies because it knew that having a drug on a hospital's formulary, or in the case of a tiered formulary, at a preferred tier or level, necessarily means materially greater use of the product, and thus increased sales and market share for the drug manufacturer, especially when there is the potential for "spillover" use of the drug after a patient is discharged from the hospital. As Bristol knew and intended, getting hospitals to place Pravachol in an unrestricted formulary position would cause spillover of Pravachol prescriptions into the community when patients were discharged from the hospital on Pravachol and proceeded to take the drug for months or years at a cost of over two dollars per pill. In fact, it is out-patient sales which routinely account for the lion's share of sales and revenue in the case of statin drugs such as Pravachol because statins are often taken on a long term basis.

7. Because the heavily discounted prices for Pravachol which Bristol offered to private hospitals were expressly conditioned on favorable formulary positioning, however, Bristol could not exclude these prices as being "merely" nominal under the Medicaid Rebate Statute. Bristol should have given the Medicaid Program the benefit of these extremely low prices in the form of increased Medicaid rebates as required by the Medicaid Rebate Statute. By knowingly failing to do so, Bristol has caused the Federal and State governments to pay far more for Pravachol then they should have, has caused the submission of false statements and records to the Federal and State Government and has made false statements and records to the Federal and State Governments to decrease the rebates due under the Medicaid rebate program.

II.
THE PARTIES

8. The United States is a plaintiff to this action. At all times material to this civil action, the United States Department of Health and Human Services ("HHS"), the Health Care Financing Administration ("HCFA"), and its successor agency the Center for Medicare and Medicaid Services ("CMS") were agencies and instrumentalities of the United States and their activities, operations and contracts in administering the Medicare and Medicaid Programs were paid from United States Funds.

9. The State of California ("California") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Defendant Bristol's Pravachol drug was provided to Medicaid recipients in California and was a covered Medicaid benefit under California's Medi-Cal Program.

10. The District of Columbia is a Plaintiff to this action. Throughout the relevant time periods specified herein, Defendant Bristol's Pravachol drug was provided to Medicaid recipients in the District of Columbia and was a covered Medicaid benefit under the District of Columbia's Medicaid Program.

11. The State of Delaware ("Delaware") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Defendant Bristol's Pravachol drug was provided to Medicaid recipients in Delaware and was a covered Medicaid benefit under Delaware's Medicaid Program.

12. The State of Florida ("Florida") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Defendant Bristol's Pravachol drug was provided to

Medicaid recipients in Florida and was a covered Medicaid benefit under Florida's Medicaid Program.

13. The State of Hawaii ("Hawaii") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Defendant Bristol's Pravachol drug was provided to Medicaid recipients in Hawaii and was a covered Medicaid benefit under Hawaii's Medicaid Program.

14. The state of Illinois ("Illinois") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Defendant Bristol's Pravachol drug was provided to Medicaid recipients in Illinois and was a covered Medicaid benefit under Illinois' Medicaid Program.

15. The Commonwealth of Massachusetts ("Massachusetts") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Defendant Bristol's Pravachol drug was provided to Medicaid recipients in Massachusetts and was a covered Medicaid benefit under Massachusetts' Medicaid Program.

16. The State of Nevada ("Nevada") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Defendant Bristol's Pravachol drug was provided to Medicaid recipients in Nevada and was a covered Medicaid benefit under Nevada's Medicaid Program.

17. The State of New Mexico ("New Mexico") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Defendant Bristol's Pravachol drug was provided to Medicaid recipients in New Mexico and was a covered Medicaid benefit under New Mexico's Medicaid Program.

18. The State of New York ("New York") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Defendant Bristol's Pravachol drug was provided to Medicaid recipients in New York and was a covered Medicaid benefit under New York's Medicaid Program.

19. The State of Tennessee ("Tennessee") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Defendant Bristol's Pravachol drug was provided to Medicaid recipients in Tennessee and was a covered Medicaid benefit under Tennessee's Medicaid Program.

20. The State of Texas ("Texas") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Defendant Bristol's Pravachol drug was provided to Medicaid recipients in Texas and was a covered Medicaid benefit under Texas' Medicaid Program.

21. The State of Wisconsin ("Wisconsin") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Defendant Bristol's Pravachol drug was provided to Medicaid recipients in Wisconsin and was a covered Medicaid benefit under Wisconsin's Medicaid Program.

22. The Commonwealth of Virginia ("Virginia") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Defendant Bristol's Pravachol drug was provided to Medicaid recipients in Virginia and was a covered Medicaid benefit under Virginia's Medicaid Program.

23. Defendant, Bristol-Myers Squibb Company ("Bristol"), is a corporation organized under the laws of Delaware and headquartered in New York City, New York. At all

times material to this civil action, Bristol has transacted business in the Federal Judicial District of Massachusetts by, including but not limited to, selling and distributing its drugs, including Pravachol, to purchasers within the District of Massachusetts.

24. Relator, Lauren Kieff, is a citizen of the United States and a resident of the Commonwealth of Massachusetts. Relator has standing to bring this action pursuant to 31 U.S.C. §3730(b)(1) and the State False Claims Acts. Ms. Kieff brings this action on behalf of each Relator State named herein for violations of the Federal False Claims Act as well as for violations of its respective State False Claims Act.

25. Ms. Kieff received her undergraduate degree from the University of Pennsylvania and a Master's Degree in Public Health from Boston University School of Public Health. From 1989 through the present (with a 10 month hiatus to earn her Master's Degree), Relator has been employed by AstraZeneca Pharmaceuticals, LP ("AstraZeneca") in positions ranging from hospital sales representative to medical information scientist covering regional and national managed care accounts. Currently, Ms. Kieff concentrates on the sale of AstraZeneca respiratory and psychiatric drugs. In her former position as a hospital-based pharmaceutical sales specialist she participated in the sale of gastrointestinal and cardiovascular AstraZeneca products, including Pravachol's competitor, Crestor, to teaching institutions located in Massachusetts (Boston area) and Rhode Island, such as Massachusetts General and New England Medical Center. In the course of her employment, Relator sought to inform herself as to the market strategies being implemented by competing drug companies with respect to gastrointestinal and cardiovascular drugs, especially at hospitals. Routine communications made her privy to various sales and marketing methods being utilized by companies manufacturing

statin drugs, including by Defendant Bristol. Relator has had direct communications with AstraZeneca employees who shared competitive information with her, including information on Bristol's Pravachol, and a former Bristol employee who was able to verify the competitive information with a hospital sales representative at Bristol. Thus, through her employment at AstraZeneca, Relator has uncovered the Federal and State False Claims Act violations against Bristol alleged herein.

III.
JURISDICTION AND VENUE

26. Jurisdiction is founded upon the Federal False Claims Act (the "Act" or the "False Claims Act"), 31 U.S.C. § 3729 *et seq.*, specifically 31 U.S.C. § 3732(a) and (b), and also 28 U.S.C. §§ 1331, 1345, and is not barred by § 3730(e). The information upon which these allegations are based was voluntarily provided by Relator to the Federal Government prior to filing this Complaint pursuant to 31 U.S.C. §§ 3730(e)(4)(B) and 3730(b)(2). No public disclosure of the allegations or transactions on which this action is based occurred before the filing of the initial complaint in this matter or before the filing of this Complaint, and this action is not based upon a public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or General Accounting Office report hearing, audit, or investigation, or from the news media. In the alternative, should the court find that there was a public disclosure of such allegations or transactions before the filing of this action, and that this action is based on a public disclosure of such allegations or transactions, then Relator is an original source of the information on which any such publicly disclosed allegations or transactions are based, and has direct and independent knowledge of such

information, and voluntarily provided the information to the Government before filing this action. Pursuant to 31 U.S.C. § 3732(b), the Court has jurisdiction over the State False Claims Act claims alleged herein because they arise from the same transaction or occurrence as the Federal False Claims Act claims pled herein.

27. Venue in the District of Massachusetts is appropriate under 31 U.S.C. § 3732(a) and sufficient contacts exist for jurisdiction in that Defendant conducts business and sells its pharmaceuticals, including those identified in this Complaint, in the District of Massachusetts. Such drugs, as Defendant knows, 1) have been and continue to be supplied to Federal Health Care Program recipients, including Medicare and Medicaid recipients and 2) have been and continue to be the subject of claims for reimbursement made by Federal Health Care Program drug providers as well as Massachusetts Medicaid drug providers, including hospitals and pharmacies.

28. A copy of this initial Complaint in this matter and written disclosures of substantially all material evidence and information Relator possesses was served on the Government pursuant to Rule 4(d)(4) of the Federal Rules of Civil Procedure, prior to the filing of this the initial Complaint *in camera* and under seal by delivering a copy of this the initial Complaint, material evidence and information to the United States Attorney for the District of Massachusetts and by sending a copy of the initial Complaint, material evidence and information by certified mail to the Attorney General of the United States in Washington, District of Columbia and to the Attorneys General for California, the District of Columbia, Delaware, Florida, Hawaii, Illinois, Massachusetts, Nevada, New Mexico, New York, Tennessee, Texas, Virginia and Wisconsin; and to the Chief Financial Officer of the Florida Department of

Financial Services and to the Secretary of the New Mexico Human Services Department. A copy of this Complaint and written disclosures of substantially all material evidence and information Relator possesses were served on the Government and on the Relator States named herein, prior to the filing of this Complaint *in camera* and under seal by delivering a copy of the Complaint , material evidence and information to the United States Attorney for the District of Massachusetts and by sending a copy of this Complaint, material evidence and information by certified mail to the Attorney General of the United States in Washington, District of Columbia; to the Attorneys General for California, Delaware, The District of Columbia, Florida, Hawaii, Illinois, Massachusetts, Nevada, New Mexico, New York, Tennessee, Texas, Virginia and Wisconsin; and to the Chief Financial Officer of the Florida Department of Financial Services and the Secretary of the New Mexico Human Services Department.

IV.
THE RELEVANT
FEDERAL HEALTH CARE PROGRAMS

29. The Federal health care programs referred to herein ("Federal Health Care Programs") are defined as follows (consistent with the definition provided in 42 U.S.C. § 1320a-7b(f)): "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government" including, among others, Medicare, Medicaid and Section 340B entities.

A. The Medicare Program

30. The United States, through the Department of Health and Human Services ("HHS"), administers the Hospital Insurance Program for the Aged and Disabled established by Part A and the Supplementary Medical Insurance Program established by Part B, Title XVIII, of

the Social Security Act under 42 U.S.C. §§ 1395 *et seq.* (the "Medicare Program").

31. The Medicare Program is the federally financed health insurance system for persons who are aged 65 and over and for those who are disabled. Medicare makes payments under Part A and Part B using private companies and insurance companies who provide these services under a contract with CMS, the Centers for Medicare and Medicaid Services (formerly HCFA).

32. At all relevant times, Bristol's Pravachol was a covered Medicare Program benefit when provided to a Medicare recipient in an in-patient setting. However, when prescribed by a doctor to a Medicare beneficiary on an out-patient basis, the cost of Pravachol was generally not reimbursed by Medicare although exceptions existed, in certain instances, as in the case of some patients in nursing home facilities.

33. At all relevant times, when hospitals provided Pravachol on an in-patient basis to Medicare beneficiaries, they were paid set amounts from the Medicare program based on the nature of the illness being treated. Such amounts encompassed, among other items, payment for any drugs administered.

B. The Medicaid Program

34. The United States Government partially funds state sponsored medical assistance programs for the poor pursuant to the Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. § 1396 *et seq.* (the "Medicaid Program"). Enacted in 1965, the Medicaid Program functions as a jointly-funded cooperative undertaking between the Federal and State Governments. Each State administers its own Medicaid program, but the State's programs are governed by Federal statutes, regulations and guidelines.

35. Benefits for drugs are optional but all States, including those named herein, have opted to provide Medicaid drug reimbursement coverage.

36. The Federal portion of States' Medicaid payments, the Federal Medical Assistance Percentage ("FMAP"), is based on a State's per capita income compared to the national average. During the relevant time period, the Federal portion consisted of a minimum of 50% up to a maximum of roughly 80%.

37. The States (and the District of Columbia) are required to implement a State Health Plan containing certain specified minimum criteria for coverage and payment of claims in order to qualify for Federal funds for Medicaid expenditures. 42 U.S.C. § 1396a(a)(30)(A).

38. At all relevant times, the cost of providing Bristol's Pravachol drug to Medicaid recipients was covered by many States' Medicaid Programs, including each of the Medicaid Programs for the Relator States.

C. The Medicaid Rebate Program

39. After hearings in 1989, Congress concluded that the Federal government, as the largest payor for prescription drugs, was paying significantly more under the State's Medicaid Programs than certain private payors. *See, e.g., Skyrocketing Drug Prices: Hearings Before the Special Committee on Aging*, United States Senate, 101st Congress, 290-297 (1989).

40. Congress addressed this inequity in 1990, by establishing the Medicaid Rebate Program (also referred to herein as the "Rebate Program"). The intention of the Rebate Program is to reduce government spending on Medicaid prescription drugs. The Rebate Program is designed to achieve this goal by giving the State Medicaid Programs the "benefit of the best price for which a manufacturer [sold] a prescription drug to any ... private purchaser." H.R. Rep.

101.881 at 96 (1990). Under the Rebate Program, in order for a manufacturer's drug to be reimbursed by Medicaid, the manufacturer must enter into a Rebate Agreement with the Secretary of Health and Human Services. With respect to single source or innovator multiple source drugs under such an agreement, the manufacturer agrees to sell its drug to the Medicaid program at its "Best Price" by paying each State a quarterly rebate. 42 U.S.C. § 1396 *et seq.* At all times relevant herein, Pravachol has been a single source drug.

41. The amount received by a State in Medicaid rebates is considered a reduction in the total amount expended under any given State's plan. Therefore, the less any given State receives in Medicaid rebates, the greater the total amount expended by the State and the more the Federal Government must correspondingly pay to each State (the FMAP). 42 U.S.C. § 1396b(a)(1); 42 U.S.C. § 1396r-8(b)(1)(B).

42. Bristol has entered into such a Rebate Agreement with the Secretary of Health and Human Services and thus has agreed to comply with the Medicaid Rebate Statute by extending to the Federal and State Governments the benefit of its Best Price for each of its single source and innovator multiple source drugs, including Pravachol.

43. Throughout the relevant time period, under the Rebate Program, 1396r-8(c)(1)(A) and (B), each State's basic rebate amount for each quarterly (three month) rebate period for each dosage, form and strength of a single source drug or innovator multiple source drug has been essentially equal to the greater of: 1) Average Manufacturer Price ("AMP") minus the Best Price ("BP") or 2) 15.1% of the Average Manufacturer Price ("AMP"), times the total number of units of the drug reimbursed by the Medicaid Program.

44. Throughout the relevant time period, pursuant to 42 U.S.C. § 1396r-8(k)(1), AMP has meant, during the rebate period, "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts."

45. Pursuant to 42 U.S.C. §1396r-8(c)(1)(C), throughout the relevant time period, the Best Price was generally defined as the "lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or government entity within the United States" and included "cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section)". Further, throughout the relevant time period Best Price excluded prices that are "merely nominal in amount".

46. The Best Price is not a weighted average and a single transaction can determine the Best Price.

47. The Rebate Statute does not define the term "merely nominal in amount". However, the Secretary of Health and Human Services as set forth in the Rebate Agreement has stated that a "nominal" price must be less than 10 percent of AMP, using the AMP for the same quarter in which the drug is sold at a nominal price.

48. The Congressional intent behind the nominal price exclusion from the Best Price calculation was to maintain the practice by drug manufacturers of offering deep discounts to charitable organizations, without making the drug manufacturers pass the benefit of that charitable act onto Medicaid in the form of an extremely low Best Price.

49. At the time the Rebate Statute was enacted, drug manufacturers were aware of what the Congressional intent was behind the nominal price exclusion from the Best Price calculation.

50. The Rebate Agreement which Bristol signed states that in the absence of specific guidance on the determination of Best Price and AMP, manufacturers may make "reasonable assumptions", provided those assumptions are consistent with the "intent" of the law, regulations, and the rebate agreement. During the relevant time period, manufacturers reported their AMP's and BP's to CMS on a quarterly basis. Pursuant to the Rebate Program, throughout the relevant time period, Bristol generally reported its BP amount for Pravachol to CMS no later than 30 days after the close of each calendar quarter. *See*, 42 U.S.C. Section 1396r-8(b)(3)(A). CMS, in turn, calculated the Pravachol rebate amount as either AMP minus BP or used the 15.1% minimum for innovator drugs. CMS then forwarded the rebate figures by NDC number to each State. States are not provided with BP numbers. Each State then multiplied the rebate amount by the number of units that the State paid for during the quarter for each NDC number to determine the rebate amount due and submitted this amount to the manufacturer for payment. The manufacturer remits this payment on a quarterly basis, withholding any disputed amount.

51. All else being equal, the higher the Best Price, the lower the Medicaid Rebate a drug manufacturer must pay.

52. Pursuant to the Medicaid Rebate Program, the information which drug manufacturers disclose to CMS is confidential and cannot be disclosed in a form which discloses the identity of a specific manufacturer or wholesaler or prices charged for drugs by such manufacturers except as the Secretary determines to be necessary to carry out the Rebate Statute.

42 U.S.C. Section 1396r-8(b)(3)(D). Typically, just a handful of personnel are given access to Best Price figures within pharmaceutical companies such as Bristol. Knowledge of the figures is generally limited to the Chief Financial Officer, and a few other employees. Generally, the Best Price numbers are generated at a pharmaceutical company's headquarters, which in this case is New York City.

V.
FACTUAL ALLEGATIONS

A. Bristol Struggles To Remain Competitive In The Statin Drug Marketplace

53. As alleged herein, Bristol defrauded the Federal and State Governments by underpaying its Medicaid rebates for its drug Pravachol from as early as January 31, 2003, through at least January 31, 2005. Both before and during this two year time period, Pravachol, initially one of Bristol's most profitable drugs and a cornerstone of the Company's success, was struggling to remain competitive in the pharmaceutical marketplace. Increased competition, unfavorable comparative drug studies, and the prospect of losing patent protection in early 2006 were combining to cause a steady erosion in Pravachol's sales and market share.

54. In the 1990s, prior to the introduction of Pfizer's Lipitor into the highly profitable statin market, Bristol's Pravachol enjoyed success. Pravachol was the third-leading statin in 1995 with 20.3% share of the statin market, Mevacor at 43.3% and Zocor at 29%. When Pfizer introduced its statin Lipitor in 1997, Pravachol had 21% of the statin market. Quickly thereafter, Bristol began losing sales to the cheaper and more effective Lipitor. By 1999, Lipitor was a $4 billion drug, gaining over 40% of the United States statin market. Pravachol had dropped to 16.8% of the market by the end of the decade.

55. In 2000, the downward trend in Pravachol sales continued. In the first quarter of 2000 alone, sales of Pravachol fell 5%, while Lipitor sales rose 46% to $1.1 billion.

56. In 2001, Lipitor's market dominance continued; it generated $6.4 billion in revenues and captured over 50% of the market while Pravachol sank to 14%. In 2002, Pravachol's market share dropped further to 13%. During 2003 and 2004, (the period in which Bristol's hospital marketing strategy was executed), Pravachol's market share rose to 15%.

57. Also during this time period , new entrants began competing with the statins such as Pravachol, Lipitor and Zocor, which were already on the market . In August of 2003 AstraZeneca introduced its statin Crestor which, like Lipitor, was a more potent drug than Pravachol. In July of 2004, Merck/Schering Plough's drug Vytorin received FDA approval and the number of prescriptions being written for this drug quickly began increasing. Vytorin is a combination drug, offering not only a statin (simvastin) but also ezetimibe which selectively inhibits intestinal cholesterol.

58. Drug studies pitting Pravachol against other statins acted to diminish the medical community's perception of Pravachol's efficacy as compared to other statins. Most notably, in 1999 Bristol announced that it was sponsoring a study comparing Pravachol to Pfizer's Lipitor in order to demonstrate that even though Lipitor was better at lowering cholesterol levels, the two drugs were equivalent at preventing deaths and heart attacks. Bristol confidently called it the "Prove-It" Study.

59. But the Prove-It Study did not prove what Bristol had hoped it would. In early March 2004, Bristol announced to an audience of thousands of physicians that the two-year study showed that Lipitor was significantly better than Pravachol in preventing deaths and heart attacks.

The risk of a heart attack or similar event was 16% lower in the Lipitor group and, moreover, the differences in outcome between the two groups began to appear in as little as 30 days. The results of the Prove-It Study were published in *The New England Journal of Medicine* shortly thereafter.

60. To make matters worse, according to an article in *The International Herald Tribune* of March 10, 2004, an earlier study sponsored by Pfizer which also compared Pravachol to Lipitor found that Lipitor halted arterial plaque growth while Pravachol slowed, but did not stop it. When the results of that study were made public, "Bristol-Myers Squibb sent its sales force out to tell doctors to wait for its more definitive study [the Prove-It Study] before abandoning Pravachol."

61. While Bristol was confronting an intensely competitive statin market, it was also confronting a ticking clock. Pravachol would lose patent protection in early 2006, at which time a generic formulation of Pravachol would likely take away much of Pravachol's remaining market share. Therefore, if Bristol wished to salvage what it could of its statin market share, it had to act quickly.

62. Bristol was also facing a myriad of additional serious problems within its organization both before and during the 2003 – 2005 time period during which its Pravachol rebate fraud was taking place. The Company was experiencing weak sales of two of its biggest drugs, Taxol for cancer and Glucophage for diabetes, due to lower priced generics. It was encountering difficulty bringing new drugs to market. For instance, it was forced to withdraw its application for FDA approval for its blood pressure drug Vanlev and subsequently two large scale trials called into question its safety. More troubling still, in 2002 the Securities and Exchange Commission and the Department of Justice initiated investigations into Bristol's reporting of

inflated revenues and specifically, into whether Bristol had engaged in "channel stuffing" or pushing wholesalers to increase their inventory of Bristol's drugs in order to pump up sales figures. Bristol's CFO and president of worldwide medicines resigned that same year (two years later they were both indicted on charges of conspiracy and securities fraud). In August 2004 the SEC ordered the Company to pay $150 million to settle charges that it had falsely inflated its revenues by $1.5 billion in 2000 and 2001. Bristol also had to restate $2.5 billion in revenue and $900 million in earnings reported from 1999 through the first half of 2002. In June 2005 Bristol paid the federal government $300 million to defer prosecution for its accounting manipulations.

B. Bristol's Two-Pronged Response To Pravachol's Shrinking Market Share

1. Bristol's Multi-Faceted, Nationwide Illegal Promotion Of Pravachol For Off-Label Uses

63. Motivated by the many competitive factors threatening to dislodge Pravachol's foothold in the statin market, and the other organizational problems facing the Company, Bristol planned and executed a multi-faceted nationwide scheme to promote Pravachol for off-label uses – or, in other words, uses not approved as safe and effective by the United States Food and Drug Administration ("FDA"). This fraudulent course of conduct began at least as early as March 2001 because on March 29, 2001 the FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC") sent written notification to Bristol objecting to Bristol's dissemination of Pravachol professional and DTC (direct to consumer) informational materials that impermissibly broadened the product's approved FDA indications[1], overstated its efficacy,

[1]Under the Food, Drug and Cosmetics Act ("FDCA"), 21 U.S.C. Sections 301-97, new pharmaceutical drugs can only be marketed after the drug manufacturer has demonstrated to the satisfaction of the FDA that a drug is safe and effective for each of its intended uses. 21 U.S.C.

and made unsubstantiated efficacy claims. A second written notification to Bristol from the DDMAC to the same effect was sent on December 3, 2001.

64. On or about August 7, 2003 the DDMAC sent yet a third warning letter (the "Warning Letter") to Bristol's CEO Peter Dolan, directing Bristol to immediately stop disseminating its misleading Pravachol promotional materials and issue corrective information promptly. For example, the DDMAC ordered Bristol to immediately stop falsely claiming 1) that Pravachol was FDA-approved to reduce the risk of strokes in the general population whether or not they had clinically evident coronary heart disease and 2) that Pravachol was the only cholesterol lowering drug FDA approved for such a use. The DDMAC asserted that Bristol had engaged in:

> [A] multifaceted promotional campaign that includes widely disseminated DTC and professional materials that suggest that Pravachol is useful in a broader range of conditions or patients than has been demonstrated by substantial evidence or substantial clinical experience. Your materials suggest that Pravachol is approved to reduce the risk of stroke in patients, whether or not they have clinically evident CHD [coronary heart disease]. This suggestion is false because Pravachol has not been approved to reduce the risk of stroke in patients without clinically evident CHD. Claims that Pravachol is the only cholesterol lowering drug approved for stroke prevention in people without clinically evident CHD are also false. This suggestion is particularly troubling considering that another treatment has been shown to reduce such risks [Zocor]. Your materials also suggest that Pravachol has been approved to reduce the risk of CV [cardiovascular] events in diabetes patients, and to lower cholesterol in all borderline-high patients.

65. The DDMAC noted that the targets of Bristol's off-label campaign were both consumers and doctors:

> The multifaceted DTC campaign is directed to a diverse consumer audience through ads in various newspapers and magazines with both national and local distribution. The messages in the DTC ads also appear in Pravachol promotional

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Section 355 (a) and (d). A drug is approved for treatment of a specific condition. The specific approved uses are called the drug's "indications".

> labeling pieces that are given or sent to consumers ("fulfillment materials") and in materials disseminated to healthcare professionals. **DDMAC views this as evidence of an orchestrated campaign to disseminate violative messages.**

(emphasis added.)

66. The misleading consumer ads appeared in such widely read magazines and newspapers as *Time*, *Good Housekeeping*, *Smithsonian*, *Southern Living*, *US News & World Report*, *Reader's Digest*, *Prevention*, *The Washington Post* and *The New York Times*.

67. DDMAC concluded in the Warning Letter that Bristol was violating federal law in multiple respects:

> Your advertisements are violative of Section 502(n) of the Act [Federal Food, Drug and Cosmetic Act] and your promotional labeling is false or misleading in violation of Section 502(a) of the Act. 21 U.S.C. §352(a) and (n). Moreover, promotional claims recommending or suggesting Pravachol for a use other than that for which FDA has reviewed safety and effectiveness data create a new "intended use" for which adequate directions must be provided in product labeling. 21 U.S.C. §352(f)(l); 21 CFR 201.5, 201.100, 201.128. Absent such directions, your product is misbranded under Section 502(f)(l) of the Act. 21 U.S.C. §352(f)(l).

2. Bristol Implements A Nationwide Hospital Contracting Strategy To Induce Hospitals To Give Patients A Pravachol Prescription At Discharge In Order To Trigger A Long Term Stream Of Pravachol Revenues From Such Patients

68. In concert with promoting Pravachol for unapproved uses as a response to the drug's flagging sales, in the fourth quarter of 2002 Bristol instituted a "nominal" pricing program for Pravachol directed to acute care hospitals nationwide, including community hospitals and teaching hospitals, in an effort to position Pravachol as well as possible within hospital drug formularies. Pursuant to the Hospital Agreement (Exhibit "1"), Bristol offered hospitals the opportunity to purchase Pravachol tablets at highly discounted or "nominal" prices provided that

the hospital placed Pravachol in an unrestricted position on its drug formulary. Comparison of the prices offered per bottle of Pravachol tablets in the Hospital Agreement versus the publicly reported wholesale prices shows that the discounts being offered were approximately 93% off the wholesale list or "WAC" price (the reported price at which Bristol sold Pravachol to wholesalers). The percentage discount off of the reported average wholesale price (the reported average price at which wholesalers sold the drug) or "AWP", was even higher. The Hospital Agreement offered Pravachol for roughly 16¢ to 24¢ per pill, depending on the milligram dosage. This compares with reported 2002 WAC prices of roughly $2.22 to $3.48 per pill.

69. Hundreds of hospitals nationwide, including Morton Hospital in Taunton, Massachusetts and Sturdy Hospital in Attleboro, Massachusetts entered into the Hospital Agreement with Bristol.

70. The Hospital Agreement continued in place at least until the fourth quarter of 2004. Significantly, by conditioning its offer to sell Pravachol at such discounted prices on the hospital's agreement to place Pravachol in an unrestricted position on the hospital's formulary, Bristol sought to induce the in-patient use of Pravachol by the hospital (and thus open the door to the more lucrative out-patient use) at the expense of other statin drugs. The Agreement provided for automatic termination of the Agreement if the hospital failed to commit to maintaining Pravachol at an "unrestricted formulary position" at the hospital:

> Discount Measurement: The discounted price for Pravachol® shall begin on the Effective Date and continue for the duration of Hospital's commitment to an unrestricted formulary position. Hospitals failing to achieve their commitment to an unrestricted formulary position for Pravachol will have their contracts terminated.
>
> *See*, Exhibit 1 at p. 1885.

71. Typically hospitals would have at most only two statins on their approved formulary. Each hospital that entered into the Agreement was agreeing to provide Pravachol with a far better competitive position in the hospital than it otherwise would have obtained or been assigned absent the Agreement. . By way of example, Relator, while performing her job duties was advised that Cambridge Health Alliance in Massachusetts (made up of three hospitals – Cambridge Hospital, Somerville Hospital and Whidden Memorial Hospital), had added Pravachol to its formulary because it was so inexpensive and would therefore not add Crestor as a formulary statin.

72. Unrestricted formulary status means that not only must physicians be permitted to freely prescribe the drug for their patients in the hospital, the hospital must agree never to substitute Pravachol with another statin such as Crestor, Zocor or Lipitor. Statins are long term drugs, often taken for many years. If a patient was discharged from the hospital with a Pravachol prescription in hand, he would likely stay on that drug for years, at a cost of over two dollars per pill. Thus, unrestricted formulary status could mean significant revenues for Bristol for years to come.

73. Without unrestricted formulary status, Bristol's potential for significant, long term revenue streams arising from hospital patients being prescribed Pravachol upon discharge, would virtually vanish. This is because even if a physician did write a Pravachol prescription, in all likelihood the hospital would engage in the common practice of therapeutic substitution, and switch the prescription to one of the more popular or effective statins. Statins like Lipitor and Zocor, for example, were generally recognized as being more effective and were thus favored by hospitals. Relying on the Agreement, Bristol used huge price discounts as an aggressive sales

tool to maintain a foothold in the hospital statin market by getting Pravachol the most favorable status possible on hospital formularies, thereby increasing the potential for the long term revenue stream which would result when a patient was given a Pravachol prescription upon discharge. Bristol's motivation was made transparent in the fall of 2004 when, for approximately 60 days, Bristol lowered the price of Pravachol pursuant to the Agreement to just one penny for 100 pills. This was a drastic drop in price. By way of illustration, it meant that hospitals could buy Pravachol 40 mg tablets at a price equal to about 1/4340th of the reported WAC. Moreover, Bristol allowed hospitals to buy unusually large quantities of the drug, amounts sufficient to last through 2005. This strategy increased the likelihood that Pravachol would maintain a favorable position on hospital formularies throughout 2005 and thus that Bristol could maintain and/or increase Pravachol's revenues for as long as possible through April 2006, when Pravachol's patent protection expired. Favorable formulary placement was so valuable to Bristol, it was willing to essentially give a year's supply of the pills away in exchange for an unrestricted position on the hospital formulary.

74. Relator has learned that the Cambridge Health Alliance purchased an entire year's supply of Pravachol (for 2005) for just $2.53 due to the penny per 100 tablets pricing.

75. Relator has learned that one hospital, Albany Medical, located in New York State, purchased a fifteen month's supply of Pravachol in or around October 24th 2004. Purchase of over one year's worth of a drug by a hospital is highly unusual.

76. It is Relator's understanding that Bristol's hospital sales force was not notified of the special 100 pills for one penny pricing deal to hospitals for Pravachol. Bristol communicated the special pricing deal directly to wholesalers, bypassing its sales force.

C. Bristol Underpaid Its Medicaid Rebates By Falsely Inflating Its Best Prices For Pravachol When It Excluded From Its Medicaid Rebate Best Price Calculation The Discounted Prices Private Hospitals Bought Pravachol For Pursuant To The Hospital Agreement

77. From at least January 31, 2003 and continuing through at least January 31. 2005, Bristol falsely inflated its Best Price as to Pravachol in its submissions to CMS. These false reports, which contain artificially high Best Prices for Pravachol, and which were submitted to CMS quarterly starting on or around January 31, 2003, have enabled Bristol to pay smaller rebate amounts, to the direct detriment of both the Federal and State Governments, since the Federal and State Governments jointly fund the Medicaid Program.

1. Bristol Set The Discounts On Pravachol Within Its Hospital Agreement At Over 90% Off Of Wholesale In Order To Avoid Giving The Discount To The Medicaid Program

78. Bristol knowingly and intentionally set its discounts for Pravachol under the Hospital Agreement at over 90% off the wholesale price in order to treat the prices that participating hospitals were paying as "nominal", and thus excludable, from the Medicaid Rebate Best Price calculation. In that way, Bristol could avoid giving these large discounts to the Federal and State Governments under the Medicaid Program, thereby causing them to pay far more for Pravachol than private hospitals were paying.

79. In 1992, Congress enacted section 340B of the Public Health Service Act ("PHS Act"), 42 U.S.C. §256(b), to establish the 340B Drug Pricing Program. This program, which is managed by the Health Resources and Services Administration ("HRSA"), provides for sales of drugs at or below established ceiling prices to certain "covered entities" ("340B Entities") that

provide health care to some of the country's most disadvantaged citizens. 340B Entities include public hospitals, AIDS Drug Assistance programs and community health centers. 42 U.S.C. §256(a)(4).

80. Pursuant to the PHS Act, manufacturers sign a Pharmaceutical Pricing Agreement stipulating that they will charge 340B entities at or below a specified maximum price, tied to the Medicaid Rebate Program, for covered outpatient drug purchases. By failing to consider the discounted Pravachol prices being enjoyed by hospitals pursuant to the Agreement, Bristol was also able to charge 340B entities inflated Pravachol prices.

81. Upon information and belief, Defendant knowingly defrauded the government by submitting false pricing data and paying insufficient Medicaid rebates for Pravachol, which has caused the government to overpay for Pravachol provided to 340B Entities.

82. The price at which Pravachol was offered to hospitals was not "merely nominal", as required under the Medicaid Rebate Statute in order to be excluded from the Best Price calculation, because the hospitals were not "merely" paying Bristol a dollar amount for Pravachol which was nominal (less than 10% of AMP). Hospitals were also paying the extremely valuable consideration of placing Pravachol in a most favorable formulary position. That consideration was far more valuable to Bristol than the negligible amount of money hospitals were required to pay. Essentially, Bristol was willing to give away a year's supply of the drug to hospitals just to secure unrestricted formulary positions. This is because absent an unrestricted formulary position, Pravachol utilization within hospitals would plummet. if not vanish, due to the routine practice of therapeutic substitution. In other words, absent unrestricted formulary status, a prescription for Pravachol would be replaced by one for another

more effective or more popular statin such as Zocor or Lipitor. Once Pravachol utilization in hospitals was gone, the potential for a Pravachol prescription being given to the patient upon discharge was also gone as was the steady stream of Pravachol revenues for months or years to come which such a prescription would generate. Likewise, at a minimum, in order to enter the Hospital Agreement and get Pravachol at a fire sale price, participating hospitals carved out an exception to what was otherwise standard procedure, namely, to therapeutically substitute another more effective statin such as Lipitor, or statin with broader indications, like Zocor, for Pravachol, as well as for every other statin which was not the hospital's first choice statin. Thus, at a minimum, by using the Hospital Agreement Bristol was able to give Pravachol a competitive advantage over all the other statins which, like Pravachol, the hospital had decided against designating as its first choice statin.

83. In at least one instance, the Hospital Agreement and its conditional offer of nominally priced Pravachol induced a system of hospitals, Cambridge Health Alliance, to give the drug exclusive positioning on its formulary. Pursuant thereto, Cambridge administered Pravachol exclusively for its cardiac patients on both the in-patient and out-patient side. The sole exception to this was in the rare case of myocardial infarction (a heart attack) or severe patient failures, in which case Lipitor was administered.

84. Bristol was free to pursue a hospital contracting strategy which conditioned its heavily discounted Pravachol prices on the hospital's agreement to give Pravachol "unrestricted" formulary status in the hospital. Inclusion of the favorable formulary positioning requirement, however, meant that for purposes of the Medicaid Rebate Statute Best Price calculation, the consideration private hospitals were paying was not "merely" nominal.

85. Both before and during the time Bristol sales representatives were presenting the Hospital Agreement to hospital pharmacy directors, Bristol was simultaneously engaged in its multi-faceted, nationwide campaign to promote the off-label use of Pravachol. This off-label campaign was directed at both consumers and doctors and included not only magazine advertisements but the drug's labeling (the printed information that accompanies the drug such as the label and package insert) as well. Thus, the Hospital Agreement was part of a two-pronged Bristol hospital marketing strategy to promote Pravachol sales: 1) get the hospital pharmacy director to place the drug in an unrestricted formulary position under the Hospital Agreement, and 2) aggressively promote Pravachol for indications for which it had never received FDA approval, such as to reduce the risk of stroke among those who did not have clinically evident heart disease. Relying on this strategy, Bristol knew that if it could get the hospital physician to write the Pravachol prescription, then another statin drug such as Zocor (which *was* indicated to reduce the risk of stroke among those without clinically evident coronary heart disease), or Lipitor (a significantly more effective statin), could not be therapeutically substituted in its place, even if the Pravachol prescription was a direct result of Bristol's off-label marketing campaign.

86. Not only did Medicaid and 340B entities not get the benefit of the discounts for Pravachol offered only to hospitals, but by inducing hospitals to prescribe Pravachol at patient discharge, Bristol increased drug costs for the government, and Medicaid in particular, in yet another way and thereby again completely undermined the intent underlying the entire Medicaid Rebate Statute, which is to reduce what the government pays for Medicaid drugs. Pravachol is a weak statin and requires larger doses to approach the same efficacy as competitors such as

Lipitor. Larger doses of the drug (often 40 mg) were prescribed more frequently than was the case with its competitors such as Lipitor, Zocor and Crestor. The larger doses mean that throughout the relevant time period, the drug was more expensive than almost any other statin or statin combination, including Lipitor, which was by far the most popular drug in its class. The average cost of Lipitor per prescription was materially less than the cost of Pravachol. *See* Express Scripts Drug Report, 2004, at p. 44 (http://www.expressscripts.com/ourcompany/news/industryreports/drugtrendreport/2004).

87. Throughout the relevant time period, the statin market was overwhelmingly dominated by drugs whose prescriptions were significantly less expensive than Pravachol's. *See*, *Id.* Only Zocor was more expensive (less than 5% more expensive, however) but Zocor represented just a small percentage of the market. *Id.* At MassHealth, (Massachusetts' Medicaid), during November 2003 through March 2004, Lipitor had almost 90% of MassHealth's statin market share.

88. Throughout the relevant time period, Bristol: 1) knew that CMS used the Pravachol Best Price representations it supplied to calculate the rebate amounts; 2) knew that CMS transmitted the rebate amounts to the State Medicaid Programs which then multiplied those figures by the number of units paid for each drug; and 3) knew or recklessly disregarded the fact that the information it had supplied to CMS regarding the Best Price of Pravachol was false.

2. Millions Of Claims For Reimbursement For Pravachol Tablets Were Submitted To State Medicaid Programs Throughout The Country During 2003 and 2004

89. The CMS website provides quarterly and yearly information on Medicaid reimbursement for out-patient drugs nationally, and for each state, according to drug NDC number. With respect to the Pravachol NDC numbers at issue, on a nationwide basis, the website shows that from first quarter 2003 through fourth quarter 2004, health care providers submitted claims for reimbursement for each and every quarter, for a total of approximately 116,112,972 tablets. For each tablet, Bristol paid a corresponding rebate to the appropriate State Medicaid agency pursuant to the Medicaid Rebate Statute. For each of the Relator States, health providers submitted claims with respect to each of the Pravachol NDC numbers at issue for each and every quarter from the first quarter of 2003 through the fourth quarter of 2004. The CMS website does not include Medicaid reimbursement information for in-patient drug use.

Pravachol			
	Period Covered Yr/Qt	**Total Utilization**	**Total Utilization**
National		**2003**	**2004**
	1st Quarter	**13,938,245.64**	**14,528,379.38**
	2nd Quarter	**14,299,611.99**	**15,009,944.63**
	3rd Quarter	**14,252,183.01**	**14,406,009.96**
	4th Quarter	**14,593,288.01**	**15,085,309.90**
	Totals	57,083,328.65	59,029,643.87

90. With respect to California, the CMS data shows that for Pravachol, during the period from the first quarter of 2003 through the fourth quarter of 2004, health care providers submitted claims for reimbursement representing a total of approximately 28,515,761 tablets.

Pravachol			
State	**Period Covered Yr/Qt**	**Total Utilization**	**Total Utilization**
CA		**2003**	**2004**
	1st Quarter	**3,420,263.94**	**3,648,632.00**
	2nd Quarter	**3,976,630.00**	**3,498,422.00**
	3rd Quarter	**3,810,667.00**	**3,139,674.00**
	4th Quarter	**3,582,091.00**	**3,439,382.00**
	Totals	14,789,651.94	13,726,110.00

91. With respect to Delaware the CMS data shows that for Pravachol, during the period from the first quarter of 2003 through the fourth quarter of 2004, health care providers submitted claims for reimbursement representing a total of approximately 330,000 tablets.

Pravachol			
State	**Period Covered Yr/Qt**	**Total Utilization**	**Total Utilization**
DE		**2003**	**2004**
	1st Quarter	**39,964.00**	**38,388.00**
	2nd Quarter	**41,792.00**	**42,065.00**
	3rd Quarter	**42,447.00**	**43,281.00**
	4th Quarter	**39,680.00**	**42,383.00**
	Totals	163,883.00	166,117.00

92. With respect to the District of Columbia, the CMS data shows that for Pravachol, during the period from the first quarter of 2003 through the fourth quarter of 2004, health care providers submitted claims for reimbursement representing a total of approximately 329,195 tablets.

Pravachol			
State	**Period Covered Yr/Qt**	**Total Utilization**	**Total Utilization**
DC		**2003**	**2004**
	1st Quarter	**41,638.00**	**23,163.00**
	2nd Quarter	**42,535.00**	**45,379.00**
	3rd Quarter	**46,169.00**	**47,837.00**
	4th Quarter	**46,201.00**	**36,273.00**
	Totals	176,543.00	152,652.00

93. With respect to Florida, the CMS data shows that for Pravachol, during the period from the first quarter of 2003 through the first quarter of 2004, health care providers submitted claims for reimbursement representing a total of approximately 7,901,982 tablets.

Pravachol			
State	**Period Covered Yr/Qt**	**Total Utilization**	**Total Utilization**
FL		**2003**	**2004**
	1st Quarter	**957,411.00**	**1,006,821.00**
	2nd Quarter	**989,951.37**	**975,046.00**
	3rd Quarter	**1,030,594.09**	**959,372.00**
	4th Quarter	**1,081,387.00**	**901,400.00**
	Totals	4,059,343.46	3,842,639.00

94. With respect to Hawaii, the CMS data shows that during the period from the first quarter of 2003 through the fourth quarter of 2004, health care providers submitted claims for reimbursement for Pravachol representing a total of approximately 860,608 tablets.

Pravachol			
State	**Period Covered Yr/Qt**	**Total Utilization**	**Total Utilization**
HI		**2003**	**2004**
	1st Quarter	**105,168.00**	**104,200.00**
	2nd Quarter	**107,308.00**	**110,571.00**
	3rd Quarter	**109,717.50**	**107,296.00**
	4th Quarter	**113,301.50**	**103,046.00**
	Totals	435,495.00	425,113.00

95. With respect to Illinois, the CMS data shows that during the period from the first quarter of 2003 through the fourth quarter of 2004, health care providers submitted claims for reimbursement for Pravachol representing a total of approximately 1,730,973 tablets.

Pravachol			
State	**Period Covered Yr/Qt**	**Total Utilization**	**Total Utilization**
IL		**2003**	**2004**
	1st Quarter	**318,466.00**	**74,716.00**
	2nd Quarter	**201,210.00**	**234,026.00**
	3rd Quarter	**228,729.00**	**240,472.00**
	4th Quarter	**108,625.00**	**324,729.00**
	Totals	857,030.00	873,943.00

96. With respect to Massachusetts, the CMS data shows that for Pravachol, during the period from the first quarter of 2003 through the fourth quarter of 2004, health care providers submitted claims for reimbursement representing a total of approximately 469,003 tablets.

Pravachol			
State	**Period Covered Yr/Qt**	**Total Utilization**	**Total Utilization**
MA		**2003**	**2004**
	1st Quarter	**174,419.00**	**18,469.00**
	2nd Quarter	**125,103.00**	**20,003.00**
	3rd Quarter	**63,135.00**	**19,453.00**
	4th Quarter	**25,793.00**	**22,628.00**
	Totals	388,450.00	80,553.00

97. With respect to Nevada, the CMS data shows that during the period from the first quarter of 2003 through the fourth quarter of 2004, health care providers submitted claims for reimbursement for Pravachol representing a total of approximately 267,225 tablets.

Pravachol			
State	**Period Covered Yr/Qt**	**Total Utilization**	**Total Utilization**
NV		**2003**	**2004**
	1st Quarter	**38,158.00**	**37,693.00**
	2nd Quarter	**34,718.06**	**35,642.00**
	3rd Quarter	**43,953.06**	**36,379.00**
	4th Quarter	**36,043.00**	**4,639.00**
	Totals	152,872.12	114,353.00

98. With respect to New Mexico, the CMS data shows that during the period from the first quarter of 2003 through the fourth quarter of 2004, health care providers submitted claims for reimbursement for Pravachol representing a total of approximately 157,481 tablets.

Pravachol			
State	**Period Covered Yr/Qt**	**Total Utilization**	**Total Utilization**
NM		**2003**	**2004**
	1st Quarter	**20,812.00**	**19,499.00**
	2nd Quarter	**21,508.00**	**19,389.00**
	3rd Quarter	**21,685.00**	**18,362.00**
	4th Quarter	**20,926.00**	**15,300.00**
	Totals	84,931.00	72,550.00

99. With respect to New York the CMS data shows that during the period from the first quarter of 2003 through the fourth quarter of 2004, health care providers submitted claims for reimbursement for Pravachol representing a total of approximately 15,254, 875 tablets.

Pravachol			
State	**Period Covered Yr/Qt**	**Total Utilization**	**Total Utilization**
NY		**2003**	**2004**
	1st Quarter	**1,881,217.00**	**1,890,745.00**
	2nd Quarter	**1,926,577.00**	**1,884,894.00**
	3rd Quarter	**1,975,476.00**	**1,857,491.00**
	4th Quarter	**1,988,995.00**	**1,849,480.00**
	Totals	7,772,265.00	7,482,610.00

100. With respect to Tennessee, the CMS data shows that during the period from the first quarter of 2003 through the fourth quarter of 2004, health care providers submitted claims for reimbursement representing a total of approximately 8,174,306 tablets.

Pravachol			
State	**Period Covered Yr/Qt**	**Total Utilization**	**Total Utilization**
TN		**2003**	**2004**
	1st Quarter	**268,634.00**	**1,423,894.00**
	2nd Quarter	**299,993.00**	**1,480,074.00**
	3rd Quarter	**496,210.00**	**1,521,803.00**
	4th Quarter	**1,164,562.00**	**1,519,136.00**
	Totals	2,229,399.00	5,944,907.00

101. With respect to Texas, the CMS data shows that during the period from the first quarter of 2003 through the fourth quarter of 2004, health care providers submitted claims for reimbursement for Pravachol representing a total of approximately 8,472,042 tablets.

Pravachol			
State	**Period Covered Yr/Qt**	**Total Utilization**	**Total Utilization**
TX		**2003**	**2004**
	1st Quarter	**797,865.00**	**801,879.00**
	2nd Quarter	**797,070.00**	**1,440,612.00**
	3rd Quarter	**785,407.00**	**1,570,550.00**
	4th Quarter	**750,379.00**	**1,528,280.00**
	Totals	3,130,721.00	5,341,321.00

102. With respect to Virginia, the CMS data shows that for Pravachol, during the period starting from the first quarter of 2003 through the fourth quarter of 2004, health care

providers submitted claims for reimbursement representing a total of approximately 2,105,599 tablets.

Pravachol			
State	**Period Covered Yr/Qt**	**Total Utilization**	**Total Utilization**
VA		**2003**	**2004**
	1st Quarter	**190,375.00**	**269,447.00**
	2nd Quarter	**186,088.00**	**326,580.00**
	3rd Quarter	**205,160.00**	**336,483.00**
	4th Quarter	**224,895.30**	**366,571.50**
	Totals	806,518.30	1,299,081.50

103. With respect to Wisconsin, the CMS data shows that for Pravachol, during the period starting from the first quarter of 2003 through the fourth quarter of 2004, health care providers submitted claims for reimbursement representing a total of approximately 2,177,497 tablets.

Pravachol			
State	**Period Covered Yr/Qt**	**Total Utilization**	**Total Utilization**
WI		**2003**	**2004**
	1st Quarter	**252,747.00**	**285,338.00**
	2nd Quarter	**260,542.00**	**278,398.00**
	3rd Quarter	**269,787.00**	**280,285.00**
	4th Quarter	**264,567.00**	**285,833.00**
	Totals	1,047,643.00	1,129,854.00

COUNT I
VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT,
31 U.S.C. §§ 3729 ET SEQ.

FALSE CLAIMS ACT; MAKING, USING, OR CAUSING TO BE MADE OR USED, A FALSE RECORD OR STATEMENT TO GET A FALSE OR FRAUDULENT CLAIM PAID OR APPROVED BY THE GOVERNMENT

104. Relator realleges and incorporates by reference paragraphs 1 through 104 as if fully set forth herein and further alleges as follows:

105. From January of 2003 and continuing throughout approximately January of 2005, Defendant knowingly [as defined in §3729(b)] has made, used and caused to be made or used, false records or statements to get false or fraudulent claims to be paid or approved by the Government, in that Defendant submitted false information to CMS on a quarterly basis. as set forth herein, regarding the Best Price of Pravachol. By reporting this false information, Defendant Bristol underpaid its Medicaid rebate obligation and caused corresponding increases in the periodic calculations of drug reimbursement costs prepared and submitted by each State's Medicaid Program to the federal government pursuant to 42 U.S.C. § 1396(b) (the "Submissions"), which are used by the federal government to calculate the federal funding due each State's Medicaid drug reimbursement program. The Submissions thereby each constitute a false claim pursuant to the False Claims Act, 31 U.S.C. § 3729(a)(2).

106. None of the States or State Medicaid Programs had any knowledge that Defendant had provided to CMS the false information that is the subject of this Complaint, and none of the States or State Medicaid Programs had any knowledge that their respective Submissions were rendered false thereby.

107. Defendant Bristol knew that the information it supplied to CMS was utilized by the United States and the State Governments to determine the required amount of rebate that each drug manufacturer had to pay to each State's Medicaid Program for Pravachol. Defendant also knew that by submitting the false information at issue here, Defendant fraudulently reduced and underpaid its rebate obligations and caused each State's Submissions to be falsely inflated, thus resulting in great financial loss to both the United States and State Governments.

108. Because of Defendant's conduct as set forth in this Count, the United States and the State Governments suffered actual damages in excess of One Million Dollars ($1.000.000.00), all in violation of 31 U.S.C. § 3729(a)(2).

COUNT II

FALSE CLAIMS ACT; MAKING, USING, OR CAUSING TO BE MADE OR USED, A FALSE RECORD OR STATEMENT TO CONCEAL, AVOID, OR DECREASE AN OBLIGATION TO PAY OR TRANSMIT MONEY OR PROPERTY TO THE GOVERNMENT

109. Relater realleges and incorporates by reference paragraphs 1 through 104 as if fully set forth herein and further alleges as follows:

110. From on or around January 31, 2003 and continuing until on or around January of 2005. Defendant knowingly [as defined in § 3729(b)] has made, used, and caused to be made and used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government. Defendant Bristol knew its obligation under the Medicaid Rebate Program, 42 U.S.C. 1396r-8, to make and use truthful records or statements regarding its drugs. Defendant also knew that the information it submitted to CMS (which was generally submitted within 30 days of the close of each calendar quarter) regarding the Best Price of Pravachol was utilized by the United States and the State Governments to determine the

required amount of rebate that Bristol had to pay to each State's Medicaid Programs for Pravachol. Defendant has made, used or caused to be made or used, false records or statements regarding Pravachol in order to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State Medicaid Programs, which are jointly funded by the United States and the States, thus directly resulting in great financial loss to the United States and the State Governments. Defendant has caused false statements and records to be made or used to decrease its Medicaid Rebate obligation to pay money or property to the federally funded State Medicaid Programs and to avoid fulfilling its obligations to covered entities under Section 340B of the Public Health Service Act by falsely overstating its Best Price with respect to Pravachol in its quarterly rebate submissions to CMS. By engaging in the conduct outlined above. Defendant thus has caused great financial loss to the United States and the State Governments.

111. Because of Defendant's conduct as set forth in this Count, the United States and the State Governments suffered actual damages in excess of One Million Dollars ($1.000.000.00), all in violation of 31 U.S.C. § 3729(a)(7).

COUNT III
VIOLATIONS OF
THE CALIFORNIA FALSE CLAIMS ACT,
CAL. GOV'T CODE §§ 12650 ET SEQ.

FALSE CLAIMS ACT; MAKING, USING, OR CAUSING TO BE MADE OR USED, A FALSE RECORD OR STATEMENT TO CONCEAL, AVOID, OR DECREASE AN OBLIGATION TO PAY OR TRANSMIT MONEY OR PROPERTY TO THE GOVERNMENT

112. Relator realleges and incorporates by reference paragraphs 1 through 104 as if fully set forth herein and further alleges as follows:

113. From January 2003, and continuing throughout approximately January of 2005, Defendant knowingly has made, used, and caused to be made and used, false statements or representations by falsely overstating its Best Price with respect to Pravachol in order to decrease its Medicaid rebate obligations under the Medicaid Rebate Program, 42 U.S.C. 1396r-8, and its rebate obligations to California pursuant to Medi-Cal in violation of Cal. Gov't Code § 12651(a)(7).

114. Because of the Defendant's conduct as set forth in this Count, California has suffered actual damages in excess of Two Hundred Thousand Dollars ($200,000.00), all in violation of Cal. Gov't Code § 12651(a)(7).

COUNT IV
VIOLATIONS OF
THE DELAWARE FALSE CLAIMS AND REPORTING ACT,
DEL. CODE ANN. TIT. 6, §§1201 ET SEQ.

FALSE CLAIMS AND REPORTING ACT; MAKING, USING, OR CAUSING TO BE MADE OR USED, A FALSE RECORD OR STATEMENT TO CONCEAL, AVOID, OR DECREASE AN OBLIGATION TO PAY OR TRANSMIT MONEY OR PROPERTY TO THE GOVERNMENT

115. Relator realleges and incorporates by reference paragraphs 1 through 104 as if fully set forth herein and further alleges as follows:

116. From January 2003, and continuing until approximately January of 2005, Defendant knowingly has made, used, and caused to be made and used, false statements or representations by falsely overstating its Best Price with respect to Pravachol in order to decrease its Medicaid rebate obligations under the Medicaid Rebate Program, 42 U.S.C. 1396r-8, and its rebate obligations to Delaware in violation of Del. Code Ann. tit. 6, §1201(a)(7).

117. Because of the Defendant's conduct as set forth in this Count, Delaware has suffered actual damages in excess of Ten Thousand Dollars ($10,000.00), all in violation of Del. Code Ann. tit. 6, §1201(a)(7).

COUNT V
VIOLATIONS OF THE DISTRICT OF COLUMBIA FALSE CLAIMS ACT,
D.C. CODE ANN. §§20308.03 ET SEQ.

FALSE CLAIMS ACT; MAKING, USING, OR CAUSING TO BE MADE OR USED, A FALSE RECORD OR STATEMENT TO CONCEAL, AVOID, OR DECREASE AN OBLIGATION TO PAY OR TRANSMIT MONEY OR PROPERTY TO THE GOVERNMENT

118. Realtor realleges and incorporates by reference paragraphs 1 through 104 as if fully set forth herein and further alleges as follows:

119. From January 2003, and continuing throughout January of 2005, Defendant knowingly has made, used, and caused to be made and used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the District of Columbia by falsely overstating its Best Price with respect to Pravachol in order to decrease its Medicaid rebate obligations under the Medicaid Rebate Program, 42 U.S.C. § 1396r-8, and its rebate obligations to the District of Columbia in violation of D.C. Code Ann. § 2-308.14(a)(7).

120. Because of the Defendant's conduct as set forth in this Count, the District of Columbia has suffered actual damages in excess of Ten Thousand Dollars ($10,000.00), all in violation of D.C. Code Ann. § 2-308.14(a)(7).

COUNT VI
VIOLATIONS OF THE FLORIDA FALSE CLAIMS ACT, FLA. STAT. §§ 68.081 ET SEQ.

FALSE CLAIMS ACT; MAKING, USING, OR CAUSING TO BE MADE OR USED, A FALSE RECORD OR STATEMENT TO CONCEAL, AVOID, OR DECREASE AN OBLIGATION TO PAY OR TRANSMIT MONEY OR PROPERTY TO AN AGENCY

121. Relator realleges and incorporates by reference paragraphs 1 through 104 as if fully set forth herein and further alleges as follows:

122. From January 2003, and continuing throughout January of 2005, Defendant knowingly has made, used, and caused to be made and used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to Florida's Medicaid Program by falsely overstating its Best Price with respect to Pravachol in order to decrease its Medicaid rebate obligations under the Medicaid Rebate Program, 42 U.S.C. 1396r-8, and its rebate obligations to Florida in violation of Fla. Stat. § 68.082(2)(g).

123. Because of the Defendant's conduct as set forth in this Count. Florida has suffered actual damages in excess of One Hundred Thousand Dollars ($100,000.00), all in violation of Fla. Stat. § 68.082(2)(g).

COUNT VII
VIOLATIONS OF THE HAWAII FALSE CLAIMS ACT, HAW. REV. STAT. §§ 661-22 ET SEQ.

FALSE CLAIMS ACT; MAKING, USING, OR CAUSING TO BE MADE OR USED, A FALSE RECORD OR STATEMENT TO CONCEAL, AVOID, OR DECREASE AN OBLIGATION TO PAY OR TRANSMIT MONEY OR PROPERTY TO THE GOVERNMENT

124. Relator realleges and incorporates by reference paragraphs 1 through 104 as if fully set forth herein and further alleges as follows:

125. From the effective date of the Hawaii False Claims Act, and continuing to approximately January 2005, Defendant knowingly has made, used, and caused to be made and used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to Hawaii by falsely overstating its Best Price with respect to Pravachol in order to decrease its Medicaid rebate obligations under the Medicaid Rebate Program, 42 U.S.C. § 1396r-8, and its rebate obligations to Hawaii in violation of Haw. Rev. Stat. § 661-21(a)(7).

126. Because of the Defendant's conduct as set forth in this Count, Hawaii has suffered actual damages in excess of Ten Thousand Dollars ($10,000.00) all in violation of Haw. Rev. Stat. § 661-21(a)(7).

COUNT VIII
VIOLATIONS OF
THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT, 740 ILL. COMP. STAT. ANN. §§ 175/1 ET SEQ.

FALSE CLAIMS ACT; MAKING, USING, OR CAUSING TO BE MADE OR USED, A FALSE RECORD OR STATEMENT TO CONCEAL, AVOID, OR DECREASE AN OBLIGATION TO PAY OR TRANSMIT MONEY OR PROPERTY TO THE GOVERNMENT

127. Relator realleges and incorporates by reference paragraphs 1 through 104 as if fully set forth herein and further alleges as follows:

128. From on or about January 2003 until approximately January of 2005, Defendant knowingly has made, used, and caused to be made and used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to Illinois by falsely overstating its Best Price with respect to Pravachol in order to decrease its Medicaid rebate obligations under the Medicaid Rebate Program, 42 U.S.C. § 1396r-8, and its rebate obligations to Illinois in violation of 740 Ill. Comp. Stat. Ann. § 175/3(a)(7)

129. Because of the Defendant's conduct as set forth in this Count, Illinois has suffered actual damages in excess of Twenty Thousand Dollars ($20,000.00), all in violation of 740 Ill. Comp. Stat. Ann. § 175/3(a)(7).

COUNT IX
VIOLATIONS OF THE MASSACHUSETTS FALSE CLAIMS ACT, MASS. ANN. LAWS. CH. 12, §§ 5A ET SEQ.

FALSE CLAIMS ACT; MAKING, USING, OR CAUSING TO BE MADE OR USED, A FALSE RECORD OR STATEMENT TO CONCEAL, AVOID, OR DECREASE AN OBLIGATION TO PAY OR TRANSMIT MONEY OR PROPERTY TO THE GOVERNMENT

130. Relator realleges and incorporates by reference paragraphs 1 through 104 as if fully set forth herein and further alleges as follows:

131. From on or about January 2003 and continuing until approximately January of 2005, Defendant knowingly has made, used, and caused to be made and used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Commonwealth of Massachusetts by falsely overstating its Best Price with respect to Pravachol in order to decrease its Medicaid rebate obligations under the Medicaid Rebate Program, 42 U.S.C. §1396r-8, and its rebate obligations to Massachusetts in violation of Mass. Ann. Laws Ch. 12, § 5B(8).

132. Because of the Defendant's conduct as set forth in this Count, Massachusetts has suffered actual damages in excess of Ten Thousand Dollars ($10,000.00), all in violation of Mass. Ann. Laws Ch. 12, §5B(8).

COUNT X
VIOLATIONS OF THE NEVADA FALSE CLAIMS ACT, NEV. REV. STAT §§357.010 ET SEQ.

FALSE CLAIMS ACT; MAKING, USING, OR CAUSING TO BE MADE OR USED, A FALSE RECORD OR STATEMENT TO CONCEAL, AVOID, OR DECREASE AN OBLIGATION TO PAY OR TRANSMIT MONEY OR PROPERTY TO THE STATE

133. Relator realleges and incorporates by reference paragraphs 1 through 104 as if fully set forth herein and further alleges as follows:

134. From on or about January of 2003 until approximately January of 2005, Defendant knowingly has made, used, and caused to be made and used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to Nevada by falsely overstating its Best Price with respect to Pravachol in order to decrease its Medicaid rebate obligations under the Medicaid Rebate Program, 42 U.S.C. 1396r- 8, and its rebate obligations to Nevada in violation of Nev. Rev. Stat. §357.040(1)(g).

135. Because of the Defendant's conduct as set forth in this Count, Nevada has suffered actual damages in excess of Five Thousand Dollars ($5,000.00), all in violation of Nev. Rev. Stat. §357.040(1)(g).

COUNT XI
VIOLATIONS OF THE NEW MEXICO FALSE CLAIMS ACT, N.M. Stat. Ann. §§ 27-14-1 ET SEQ. H. 468, 46TH LEG., 2d REG. SESS. (N.M. 2004) (CODIFIED AT N.M. STAT. ANN. §§ 27-14-1 ET SEQ.)

FALSE CLAIMS ACT; MAKING, USING, OR CAUSING TO BE MADE OR USED, A FALSE RECORD OR STATEMENT TO CONCEAL, AVOID, OR DECREASE AN OBLIGATION TO PAY OR TRANSMIT MONEY OR PROPERTY TO THE GOVERNMENT

136. Relator realleges and incorporates by reference paragraphs 1 through 104 as if fully set forth herein and further alleges as follows:

137. From the effective date of the New Mexico False Claims Act until approximately January of 2005, Defendant knowingly has made, used, and caused to be made and used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to New Mexico by falsely overstating its Best Price with respect to Pravachol in order to decrease its Medicaid rebate obligations under the Medicaid Rebate Program, 42 U.S.C. 1396r-8, and its rebate obligations to New Mexico in violation of N.M. Stat. Ann. § 27-14-4E.

138. Because of the Defendant's conduct as set forth in this Count, New Mexico has suffered actual damages in excess of Five Thousand Dollars ($5,000.00), all in violation of N.M. Stat. Ann. § 27-14-4E.

COUNT XII
VIOLATIONS OF THE NEW YORK FALSE CLAIMS ACT, NY CLS ST. FIN. §§187 ET SEQ.

MAKING, USING, OR CAUSING TO BE MADE OR USED, A FALSE RECORD OR STATEMENT TO CONCEAL, AVOID, OR DECREASE AN OBLIGATION TO PAY OR TRANSMIT MONEY OR PROPERTY TO STATE

139. Relator realleges and incorporates by reference paragraphs 1 through 104 as if fully set forth herein and further alleges as follows:

140. From January 2003, and continuing until approximately January of 2005, Defendant knowingly has made, used, and caused to be made and used, false statements or representations by falsely overstating its Best Price with respect to Pravachol in order to decrease its Medicaid rebate obligations under the Medicaid Rebate Program, 42 U.S.C. 1396r-8, and its rebate obligations to New York in violation of NY CLS St. Fin. § 189(1)(g).

141. Because of the Defendant's conduct as set forth in this Count, Delaware has suffered actual damages in excess of Ten Thousand Dollars ($10,000.00), all in violation of NY CLS St. Fin. § 189(1)(g).

COUNT XIII
VIOLATIONS OF THE TENNESSEE MEDICAID FALSE CLAIMS ACT, TENN. CODE ANN. §71-5-171 ET SEQ.

FALSE CLAIMS ACT; MAKING, USING, OR CAUSING TO BE MADE OR USED, A RECORD OR STATEMENT TO CONCEAL, AVOID, OR DECREASE AN OBLIGATION TO PAY OR TRANSMIT MONEY OR PROPERTY TO THE GOVERNMENT

142. Relator realleges and incorporates by reference paragraphs 1 through 104 as if fully set forth herein and further alleges as follows:

143. From the effective date of the Tennessee Medicaid False Claims Act until approximately January of 2005, Defendant knowingly has made, used, and caused to be made and used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to Tennessee by falsely overstating its Best Price with respect to Pravachol in order to decrease its Medicaid rebate obligations under the Medicaid Rebate Program, 42 U.S.C. 1396r-8, and its rebate obligations to Tennessee in violation of Tenn. Code Ann. § 71-5-182(a)(1)(D).

144. Because of the Defendant's conduct as set forth in this Count, Tennessee has suffered actual damages in excess of One Hundred Thousand Dollars ($100,000.00), all in violation of Tenn. Code Ann. § 71-5-182(a)(1)(D).

COUNT XIV XIII
VIOLATIONS OF THE TEXAS FALSE CLAIMS ACT,
TEX. HUM. RES. CODE §§36.001 ET SEQ.

FALSE CLAIMS ACT; MAKING, CAUSING TO BE MADE, INDUCING, OR SEEKING TO INDUCE THE MAKING OF A FALSE STATEMENT OR MISREPRESENTATION

145. Relator realleges and incorporates by reference paragraphs 1 through 104 as if fully set forth herein and further alleges as follows:

146. From on or about January 2003 and continuing to approximately January of 2005, Defendant knowingly has made, caused to be made, induced and sought to induce the making of false statements or representations by falsely overstating its Best Price with respect to Pravachol in order to decrease its Medicaid rebate obligations under the Medicaid Rebate Program, 42 U.S.C. 1396r-8, and its rebate obligations to Texas in violation of Tex. Hum. Res. Code §36.002(4)(B).

147. Because of the Defendant's conduct as set forth in this Count, Texas has suffered actual damages in excess of One Hundred Thousand Dollars ($100,000.00), all in violation of Tex. Hum. Res. Code §36.002(4)(B).

COUNT XIVXV
VIOLATIONS OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT, VA. CODE §§ 8.01-216.1 ET SEQ.

FALSE CLAIMS ACT; MAKING, USING, OR CAUSING TO BE MADE OR USED, A FALSE RECORD OR STATEMENT TO CONCEAL, AVOID, OR DECREASE AN OBLIGATION TO PAY OR TRANSMIT MONEY OR PROPERTY TO THE GOVERNMENT

148. Relator realleges and incorporates by reference paragraphs 1 through 104 as if fully set forth herein and further alleges as follows:

149. From the effective date of the Virginia Fraud Against Taxpayers Act, and continuing to approximately January of 2005, Defendant knowingly has made, used, and caused to be made and used, false statements or representations by falsely overstating its Best Price with respect to Pravachol in order to decrease its Medicaid rebate obligations under the Medicaid Rebate Program, 42 U.S.C. 1396r-8, and its rebate obligations to Virginia in violation of Va. Code Ann. § 8.01-216.3(A)(7).

150. Because of the Defendant's conduct as set forth in this Count, Virginia has suffered actual damages in excess of Twenty Thousand Dollars ($20,000.00), all in violation of Va. Code Ann. §8.01-216.3(A)(7).

COUNT XVI
VIOLATIONS OF THE WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE ACT, WIS. STATS. §20.931

MAKING, USING, OR CAUSING TO BE MADE OR USED, A FALSE RECORD OR STATEMENT TO CONCEAL, AVOID, OR DECREASE AN OBLIGATION TO PAY OR TRANSMIT MONEY OR PROPERTY TO STATE

151. Relator realleges and incorporates by reference paragraphs 1 through 104 as if fully set forth herein and further alleges as follows:

152. From January 2003, and continuing until approximately January of 2005, Defendant knowingly has made, used, and caused to be made and used, false statements or representations by falsely overstating its Best Price with respect to Pravachol in order to decrease its Medicaid rebate obligations under the Medicaid Rebate Program, 42 U.S.C. 1396r-8, and its rebate obligations to Wisconsin in violation of Wis. Stat. §20.931(2)(g).

153. Because of the Defendant's conduct as set forth in this Count, Wisconsin has suffered actual damages in excess of Ten Thousand Dollars ($10,000.00), all in violation of Wis. Stat. §20.931(2)(g).

REQUESTS FOR RELIEF

WHEREFORE, Relator, on behalf of the United States, The State of California, The District of Columbia, The State of Delaware, The State of Florida, The State of Hawaii, The State of Illinois, The Commonwealth of Massachusetts, The State of Nevada, The State of New Mexico, The State of New York, The State of Tennessee, The State of Texas, and The Commonwealth of Virginia and the State of Wisconsin demands that judgment be entered in their favor and against Defendant Bristol for the maximum amount of damages and such other relief as the Court may deem appropriate on each Count. This includes, with respect to the

Federal False Claims Act, three times the amount of damages to the Federal Government plus civil penalties of no more than Eleven Thousand Dollars ($11,000.00) and no less than Five Thousand Five Hundred Dollars ($5,500.00) for each false record or statement made, used, or caused to be made or used and any other recoveries provided for under the Federal False Claims Act .

Further, Relator, on her behalf, requests that she receive the maximum amount permitted by law of the proceeds of this action or settlement of this action collected by the United States and the Relator States, plus reasonable expenses necessarily incurred, and reasonable attorneys' fees and costs. Relator requests that her award be based upon the total value recovered, both tangible and intangible, including any amounts received from individuals or entities not parties to this action.

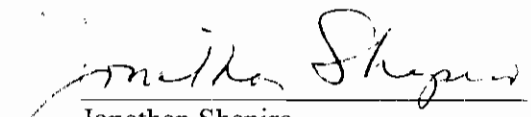
DEMAND FOR JURY TRIAL

A jury trial is demanded in this case.

Dated: January 26, 2011

Respectfully submitted,

STERN, SHAPIRO, WEISSBERG & GARIN, LLP



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